Supreme Court, U.S.
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No. 01-188

IN THE

Supreme Court of the United States

PHARMACEUTICAL RESEARCH and MANUFACTURERS OF AMERICA,
Petitioner,

v.

KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENTOF HUMAN SERVICES, and THE MAINE ATTORNEY GENERAL,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

BRIEF OF *AMICI CURIAE* MAINE COUNCIL OF SENIOR CITIZENS, VIOLA QUIRION, MICHELLE CAMPBELL AND RICHARD DONAHUE, M.D. IN SUPPORT OF KEVIN CONCANNON AND G. STEVEN ROWE AND AFFIRMANCE

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QUESTIONS PRESENTED

Amici will address both questions presented in the petition:

1. Whether the purpose of the federal Medicaid statute, 42 U.S.C. §1396 *et seq.*, is frustrated if Maine considers *any* drug for prior authorization status as a result of the drug manufacturer's choice not to negotiate with the State better prices for uninsured and underinsured consumers not eligible for Medicaid?

2. Whether Maine violates the Commerce Clause by negotiating with out-of-state manufacturers for discounts for uninsured or underinsured consumers?

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INTERESTS OF *AMICI CURIAE*

Amici Curiae are two individuals, and an association and a doctor representing individuals, who lack health insurance coverage for the cost of their prescription drugs and who intend to take advantage of benefits offered under the "Maine Rx Program" established by the statute at issue in this case. They have been granted "amicus plus" status by the United States District Court for the District of Maine in the proceedings below, in response to a motion to intervene filed subsequent to the Court's granting of a preliminary injunction. In the appeal of the District Court's decision to the First Circuit Court of Appeals, they filed an *Amici Curiae* brief. The parties have consented to this filing of an *Amici Curiae* brief.[1] *Amici* also have submitted a lodging.

Viola Quirion, who retired after 44 years of working at a shirt factory, has no health insurance coverage. She requires the drug Relafen for her arthritis and Prilosec for a hiatal hernia. Without Relafen, Ms. Quirion will rapidly lose her ability to walk and would have to go into a nursing home. She has either cut her pills or skipped pills to reduce her drug costs. She also has skipped meals and eaten the cheapest meals she can find in order to save money for medicine, but those tactics cause her other health problems. Aff. of Viola Quirion. (Addendum to First Circuit Court of Appeals *Amici Curiae* Brief at 1) (hereafter Add. of First Cir. Amici Brief).

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[1] No counsel for a party authored this brief *Amici Curiae* in whole or in part. The Alliance for Retired Americans (with which *Amicus* Maine Council of Senior Citizens is affiliated) and the American Federation of Labor and Congress of Industrial Organizations contributed to the costs of printing this brief. The American Association of Retired Persons may contribute to the cost of legal research but has not directed such research. Aside from these, no other person or entity beyond Amici and their counsel has made a monetary contribution to the preparation or submission of this brief.

Michelle Campbell is a young mother of four living in the island community of North Haven, Maine, with her children and husband. Ms. Campbell's family has no health insurance and does not qualify for Medicaid. Because her husband is a fisherman, her family's income varies by the season. Her family's income is lowest during the winter, when her children are most susceptible to illness. Her 10-year-old daughter suffers from reactive airway disease and needs inhalers that cost about $75 per month. In the winter, her daughter must take Singular, which costs another $100 per month. Aff. of Michelle Campbell (Add. of First Cir. Amici Brief at 3).

The Maine Council of Senior Citizens is a membership organization that advocates for the interests of Maine seniors. Many of the Council's members are forced to make life-threatening choices between medicine and food or heating oil. Many skip dosages, share prescriptions or don't fill their prescriptions at all. Aff. of John Moran (Add. of First Cir. Amici Brief at 5).

Richard J. Donahue, M.D., is a family practice physician at the Islands Community Medical Center in Vinalhaven, Maine. Through his practice, he is aware of patients who have refused or misused medications because of the high cost of prescription drugs. Generally, his cardiac patients and patients suffering from hypertension are more apt to base decisions regarding their medications on cost, because symptoms of those conditions are often subtle, and it is difficult for patients to justify buying drugs over other essentials when they are feeling well. Dr. Donahue believes that making drugs more affordable through the Maine Rx Program will substantially improve his patients' health. Aff. of Richard J. Donahue, M.D. (Add. of First Cir. *Amici* Brief at 7).

STATEMENT OF THE CASE

The compelling stories of *Amicus Curiae* typify those of thousands more uninsured Maine citizens who lack insurance for prescription drugs and therefore must pay out-of-pocket for their medications at some of the highest prices in the world. Widespread reports of uninsured senior citizens and other chronically ill residents not taking their prescriptions, skipping doses, or sacrificing food or heat in order to purchase medicines prompted the Maine Legislature to address the growing public health crisis in 2000 by enacting the Maine Rx Program by an overwhelming bipartisan consensus. 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599).

The Maine Rx law authorizes the State of Maine to operate as a pharmaceutical benefits manager (PBM) with the authority to negotiate prescription drug rebates to the State in order to reduce the out-of-pocket cost of drugs for Maine's uninsured population. Under the Maine Rx Program, the State links market share and volume to rebates from manufacturers, a market incentive common to private-sector PBMs and familiar to pharmaceutical manufacturers. While enrollment in the Program is open to all Maine residents, only those residents without alternative prescription drug benefits through health insurance or through some government program will benefit by enrolling.

As the First Circuit Court of Appeals recognized, the Maine Rx law "is predicated on the economic reality that volume buying of prescription drugs by Medicaid administrators, insurance companies and health maintenance organizations ('HMOs') resulted in substantially lower prices for these entities than for individual purchasers," such that individual elderly purchasers were paying 86 percent higher prices than those charged the federal government and HMOs. *Pharmaceutical Research and Mfrs. Of Am. v. Concannon*, 249 F.3d 66, 71 (1st Cir. 2001) (hereafter *PhRMA*).

Participation by drug manufacturers in the Maine Rx Program is voluntary. The statute does not attempt to regulate drug manufacturers' prices; it authorizes the State to use its market share to negotiate rebates. The Maine Commissioner of Human Services is expressly instructed by the statute to use his "*best efforts* to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medicaid program." 22 M.R.S.A. §2681(4)(B) (emphasis added). The Legislature clearly envisioned that some manufacturers will not participate. The law strengthens the bargaining position of the Commissioner by making public the names of manufacturers who elect not to enter into rebates and proposing those manufacturers' products for "prior authorization" under the State's Medicaid program, "as permitted by law." *Id.* at §2681(7). In so doing, the statute adopts a market model rather than a regulatory one; recalcitrant manufacturers face no civil or criminal penalties.

The Act creates an incentive for drug manufacturers to participate in negotiations by threatening to shift shares of Maine's Medicaid prescription drug market to competitive drugs of participating manufacturers. Drug manufacturers also anticipate that any shift in the Medicaid market will be exaggerated by a tendency among health care professionals to prescribe the same drugs to their non-Medicaid patients as they are accustomed to prescribing to their Medicaid patients.

Prior authorization is not the goal of the Maine Rx Program. If the State successfully negotiates drug rebates with manufacturers, there will be no increased use of prior authorization due to the Maine Rx Program.

Before the Maine Rx program could go into effect, the Petitioner trade group brought this facial challenge to the law and obtained a preliminary injunction in the United States District Court for the District of Maine. On appeal, the First Circuit Court of Appeals found no constitutional violation by the Maine Rx law, but stayed its mandate to permit this

appeal of a facial challenge at the preliminary injunction stage of litigation.

Although the State timely and responsibly addressed a public health crisis within its borders by enacting the Maine Rx Program, it has never had the opportunity to put the Program to the test. It has been denied the opportunity to determine what success might result from a market-model negotiation process; to demonstrate that Maine Rx will not impose a burden on Medicaid beneficiaries; and to provide the first ounce of relief to its growing population of uninsured needy, ill, and elderly people. Ironically, the Petitioner—a trade group for the industry whose pricing practices created this public health crisis by forcing Maine's uninsured to pay the highest prices—now claims to act on behalf of Maine's needy.

SUMMARY OF ARGUMENT

In this facial challenge, the Petitioner trade group cannot establish that any application of the Maine Rx Program necessarily will frustrate the congressional purpose of the joint state and federal Medicaid program in violation of the Supremacy Clause. States are expressly permitted by federal statute to require prior authorization for any prescription drug, and some states historically elected to require prior authorization for every drug. Congress was not concerned with the states' motivation for prior authorization. Furthermore, the purpose of the Maine Rx law is consistent with the purpose of the Medicaid program, and even advances that purpose, by making prescription drugs more accessible to persons lacking insurance coverage.

The Maine Rx law does not regulate the terms of out-of-state transactions or otherwise violate the dormant Commerce Clause. Rather it authorizes Maine to become a market participant by taking on the role of a pharmaceutical benefits manager (PBM) for Program enrollees, negotiating drug prices for that group in the same manner as PBMs in the

private market. Manufacturer rebates under the Maine Rx Program depend on voluntary negotiations with individual drug companies. While rebates may affect the profits of individual drug companies, that impact will not be a result of regulation but of negotiation and competition for market share.

The Petitioner's complaint does not challenge the Maine Rx Program on the basis that it requires approval by the federal government as an amendment to Maine's Medicaid plan, and that issue is not properly before this Court for review. Similarly, the Petitioner did not argue discrimination against interstate commerce in the proceedings below, and therefore waived its right to do so at this late date.

ARGUMENT

I. MAINE'S RX PROGRAM IS NOT PREEMPTED BY FEDERAL LAW.

A. The Petitioner Cannot Establish That Any Application of the Maine Rx Program Will Frustrate the Purposes of Medicaid.

The hurdle that the Maine Rx law must clear in order to pass constitutional muster under the Supremacy Clause is not a high one. The only basis asserted by the Petitioner for preemption in this case is implied conflict preemption. To prevail, the Petitioner must show that compliance with both the Maine Rx law and the federal Medicaid law is impossible, or that the Maine Rx law interposes an obstacle to the achievement of Congress' discernible objectives. *Gade v. National Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992).

Moreover, the Petitioner's challenge to the Maine Rx Program on Supremacy Clause grounds is a facial challenge, in which "the challenger must establish that no set of circumstances exists under which the Act could be valid." *United States v. Salerno*, 481 U.S. 739, 745 (1987); *see also Anderson v. Edwards*, 514 U.S. 143, 155 n.6 (1995) (citing

Salerno); *Reno v. Flores*, 507 U.S. 292, 301 (1993) (same); *Rust v. Sullivan*, 500 U.S. 173, 183 (1991) (same).

In essence, the Petitioner contends that Maine may not enlist its expressly granted authority of prior authorization within its Medicaid program to improve access to necessary health care for persons outside the Medicaid population. Consequently, the Petitioner must show that the placement of *any* drug onto the Medicaid prior authorization list, when consideration for placement was triggered by the Maine Rx Program, will frustrate the objectives of Congress to provide medical services to those persons whose "income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. §1396. It is not enough that the Petitioner establish that the *potential* exists for a State to operate the Maine Rx Program in a manner that would interfere with Congress' objectives.

Petitioner's attempt to prevent the State from implementing the Maine Rx law in order to address "one of the serious [public health] problems of our time," *PhRMA*, 249 F.3d at 80, should not be treated lightly. Protecting the health and safety of the public is traditionally a legitimate role of, and within the authority of, the State. *Hill v. Colorado*, 530 U.S. 703, 715 (2000); *Metropolitan Ins. Co. v. Mass.*, 471 U.S. 724, 758 (1985). "[T]he historic police powers of the States [are] not to be superceded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress." *New York State Conference of Blue Cross and Blue Shield Plans v. Travelers Insurance Co.*, 514 U.S. 645, 655 (1995) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

The Petitioner has failed to meet its burden. Nothing on the face of the Maine Rx statute makes it impossible to implement both that law and Medicaid or frustrates the objectives of Congress under the Medicaid program.

B. Maine Rx Serves a Purpose Consistent With Medicaid.

The State acted within its broad scope of discretion when it enacted the Maine Rx Program and, if implemented, the Program will benefit Medicaid. Indeed, the purposes of the two laws are entirely consistent. The purpose of the Medicaid program is to enable states to provide medical services to those persons whose "income and resources are insufficient to meet the costs of necessary medical services," 42 U.S.C. §1396, whereas the purpose of the Maine Rx Program is to provide "greater access to prescription drugs" by making them more affordable to uninsured or underinsured persons. 22 M.R.S.A. §2681(1). The inability of the uninsured to pay for their prescription drugs was the clear motive for enacting the Maine Rx Program. "They have to take the prescription back, go home and say, 'I just can't have it filled.'" Me. Legis. Rec. S2496 (2nd Reg. Sess. 2000) (Statement of Sen. Pingree).

Maine Rx offers a benefit to a targeted population—those who must pay out of their own pocket for prescription drugs. Although the Maine Rx Act does not impose any means test on enrollees, the de facto beneficiaries of the program are persons who are uninsured, underinsured and not eligible for Medicaid. Any person whose prescription drug costs are substantially paid by an insurer will not realize any savings by enrolling in the Maine Rx Program. Those persons with the most significant unmet need for affordable prescription drugs—primarily the elderly and those with devastating acute or chronic illnesses—are most likely to enroll in the program. This use of natural targeting offers advantages over rigid alternatives such as a means-test. It reduces bureaucratic costs and inefficiencies, renders enrollment easy, minimizes stigma, and increases flexibility for enrollees with varying incomes and health problems.

If a benefit to Medicaid need be discerned, the Maine Rx Program provides one. By making drugs more affordable to persons without Medicaid or private insurance, Maine Rx will decrease, or slow the rate of increase of, the number of Medicaid enrollees, thereby conserving resources for existing Medicaid beneficiaries.

This effect is reported in the literature of the field. When people are unable to purchase necessary medications, skip their medications for cost reasons, or choose medications over other essentials for their health, their physical conditions are likely to worsen, and they are more likely to be driven into poverty, hospitals and nursing homes. *See, e.g.*, Aff. of Viola Quirion ¶ 3 (stating that without the prescription drug Relafen, that she can ill afford, she would lose her "ability to walk in a very short time and would have to go into a nursing home") (Add. of First Cir. Amici Brief at 1); Steven B. Soumerai, Sc.D., *Effects of Medicaid Drug-Payment Limits on Admission to Nursing Homes*, 325 New Engl. J. Med. 1072 (1991) (reporting that increased prescription drug costs to frail, low-income, elderly patients increases their risk of institutionalization in nursing homes and may increase Medicaid costs) (First Cir. Amici App. at 115); Steven B. Soumerai, Sc.D., *Effects of Limiting Medicaid Drug Reimbursement Benefits on the Use of Psychotropic Agents and Acute Mental Health Services by Patients with Schizophrenia*, 331 New Engl. J. Med. 650 (1994) (reporting that increased costs of prescription drugs to low-income patients with chronic mental illnesses can increase their use of acute mental health services and increase costs to the government) (First Circuit Court of Appeals Amicus App. at 122); Alyce S. Adams, *Use of Antihypertensive Drugs by Medicare Enrollees: Does Type of Drug Coverage Matter*, Health Affairs, Jan.-Feb. 2001 (concluding that government should be quite concerned about underuse of clinically important drugs in patients without insurance coverage or

with self-purchased coverage because of increased likelihood of adverse events).

Understandably, when consumers cannot afford their medications, they don't comply with their doctors' instructions on doses, or they resort to sharing medications or self-prescribing with cheaper substitutions. Aff. of Viola Quirion at ¶ 5 (stating that she is forced to cut pills or skip dosages in order to afford her medications) (Add. of First Cir. Amici Brief at 2); Aff. of John Moran ¶ 6 (noting that members of his group skip dosages, share prescriptions or don't fill their prescriptions) (Add. of First Cir. Amici Brief at 6); *Problems With Prescription Drugs Highest Among Elderly*, American Family Physician, Dec. 1983 (noting non-compliance by elderly with their medications, by not taking the medication, not taking at the proper time or in the proper dose, swapping drugs with friends, and self-prescribing over-the-counter drugs).

The United States agrees that Medicaid is likely to benefit from making prescription drugs more affordable to non-Medicaid consumers. "A prescription drug discount for non-Medicaid populations, made possible by encouraging manufacturers to give rebates, could significantly decrease the chance that such individuals will become Medicaid-eligible as either categorically or medically needy individuals, and thereby drain the State's scarce Medicaid resources." Brief for the United States at 29; *see generally* Brief for the United States at 25-30.[2] The United States' only objections to the Maine Rx law appear to be the absence of a means test and a belief that states must obtain federal approval before implementing programs like Maine Rx.

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[2] Petitioner can hardly disagree. "The value of new and better medicines stems not only from the improved treatment of disease, but also from a reduction in other health care costs, increased productivity and better quality of life." *See* PhRMA web site at *www.phrma.org/issues/valuemedicine*.

The United States sets the bar too high. Under an implied preemption challenge, there is no requirement that the state statute benefit the federal law at issue, let alone be narrowly tailored to benefit that law.

A means test within the Maine Rx Program would not increase the benefit to Medicaid, nor lessen any burden. If there is any burden to Medicaid beneficiaries from the use of prior authorization to obtain market leverage with drug manufacturers (which Amici assert there is not), *precisely the same burden exists* irrespective whether the Maine Rx Program is targeted to a means-tested population or whether the program is of benefit to all uninsured or underinsured Maine residents. Nothing in the record suggests that not including a means test within Maine Rx results in a greater need for prior authorization under Medicaid. There simply is no correlation between the amount of benefit to the uninsured or underinsured non-Medicaid population and the amount of inconvenience, if any, to Medicaid beneficiaries.

Furthermore, when the United States contends that the Maine Rx Program insufficiently targets a needy population for affordable drugs, it takes into consideration only half of the equation—the income side—and not the extent to which drug costs may exceed the ability of many to pay. The growth in prescription drug use and costs is undeniable. A recent study found that persons who spend $5,000 or more per year are the fastest growing group among a population of insured elderly. High- and very high-cost elderly took more than 50 prescriptions per year on average. Cindy Parks, *Growth in Prescription Drug Spending Among Insured Elders: Use of Newer Classes of Medications Moves Elderly Persons Into Higher Cost Groups*, Health Affairs, Sept.-Oct. 2001. Uninsured and underinsured seniors do not have fewer prescription drug needs; they only have a lesser ability to pay.

The fact that Maine has initiated another drug assistance program with a means test (the Healthy Maine Prescription

Program, which program uses Medicaid dollars) does not place the Maine Rx Program in conflict with Medicaid's objectives. Maine would be unwise to rely upon the Healthy Maine Prescription Program alone to address the State's public health crisis, as Petitioner has filed a separate lawsuit challenging the legality of that program as well. That case is pending in the District of Columbia Circuit Court of Appeals. *Pharmaceutical Research and Mfrs. Of Am. v. Thompson*, Docket No. 02-5110. Moreover, the ease of enrollment and other qualities of the Maine Rx Program, in addition to the program's high visibility, are likely to encourage participation among persons who have not enrolled in the Healthy Maine Program. In any case, no one program will achieve 100 percent enrollment of eligible participants. *See, e.g.*, Henry J. Kaiser Family Foundation, *California Seniors and Prescription Drugs*, at 4 (2002) (finding that less than a quarter of California's senior citizens were aware of State's drug discount program enacted two years earlier) (available online at *www.kff.org*). Maine will be more successful extending benefits to the uninsured if they are given alternatives. That is not a novel concept in the world of private insurance, or in the world of other businesses, and should not be so in the arena of public health. In the absence of a necessary obstacle to Congress' objectives for Medicaid, the choice of how to fashion programs to best expand uninsured citizens' access to affordable prescription drugs is properly a policy decision left to the State, through its elected legislature.

C. The Use of Prior Authorization Is Expressly Permitted by Statute.

The use of prior authorization is not a harm to be balanced against the benefit to Medicaid from the Maine Rx Program. It instead is an appropriate tool that Congress expressly provided to the states, and which states have broad authority to manage for their purposes. The issue is not what Congress *intended* regarding the use of prior authorization, but what

authority Congress expressly *gave* the states to use prior authorization. As the First Circuit Court of Appeals concluded, the Medicaid statute does not appear concerned with the motivation behind the states' imposing prior authorization. *PhRMA*, 249 F.3d at 76 (2001).

The Medicaid statute requires states to "provide such *safeguards* as may be necessary to assure that eligibility for care and services under the plan will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients . . . ." 42 U.S.C. § 1396(a)(19) (emphasis added). "A State may subject to prior authorization *any* covered outpatient drug" provided that the State implements two safeguards. *Id.* at §1396r-8(d)(1)(A) (emphasis added) (24-hour response time and 72-hour emergency supply).

Provided these safeguards are followed, a State does not act contrary to the best interest of Medicaid beneficiaries as a whole by requiring prior authorization of selected drugs. More to the point, there is no evidence in the record to support the facial challenge that Maine *necessarily* cannot operate its Medicaid program with sufficient safeguards for prior authorization because of the Maine Rx Program.

The plain text of the Maine Rx law incorporates Medicaid's safeguards by requiring that prior authorization be used "as permitted by law." 22 M.R.S.A. §2681(7). In addition, the statute requires the Department of Human Services to administer the Maine Rx Program in a manner that is "advantageous . . . to the enrollees" in Maine's Medicaid program and that will "enhance efficiency" of that program. *Id.* at §2681(13).

The authority of a State to choose any drug or all drugs for prior authorization hardly could be more clear. Nothing in the Medicaid Act prohibits states from using prior authorization to increase efficiencies, reduce (or decrease the rate of growth of) Medicaid expenditures, to favor one brand of

drugs over another, and to favor the use of generic drugs over other drugs.[3] Significantly, when gaining these economies, states are not obligated to devote savings (or avoided costs) to extend Medicaid programs to others, or to expand the scope of Medicaid benefits to the existing Medicaid population.

If Maine has the authority to impose prior authorization for every prescription drug, then it surely has the authority to impose prior authorization on a lesser number of drugs, so long as Maine complies with other conditions of the Medicaid program. Indeed, Maine already imposes, as do other states, prior authorization requirements for numerous drugs.

Maine has never proposed—and the Maine Rx law does not require—a radical amount of prior authorization, under any scenario. Under rules proposed by the State, non-participation by a manufacturer in the Maine Rx Program may trigger a recommendation of that manufacturer's drug for prior authorization to Maine's Medicaid Drug Utilization Review Committee, an advisory board of physicians and pharmacists. The Committee will make the final determination as to prior authorization, consistent with the Medicaid law and "particularly the principle that Medicaid recipients shall be assured access to all medically necessary prescription drugs." Aff. of Kevin Concannon ¶11 (J.A. at 165, 167).

In addition to the Maine Rx law's express provision that prior authorization be used only "as permitted by law," 22 M.R.S.A. §2681(7), Maine's Commissioner of Human Services has said by affidavit in this case that the State will not violate Medicaid requirements in its use of prior authorization. "The Department will not impose a prior authorization requirement in the Medicaid program . . . where the

[3] New Haven Legal Assistance, Florida Legal Services, and National Health Law Program argue as Amici that a burden is placed on Medicaid beneficiaries by any use of prior authorization, which use is clearly permitted by Medicaid. Those Amici would like to read prior authorization out of Medicaid altogether, an issue clearly not before the Court.

imposition of such a requirement would conflict with the requirements of the Medicaid program. Prior authorization requirements will not be implemented so as to prevent Medicaid recipients from obtaining medically necessary prescription drugs." Aff. of Kevin Concannon ¶9 (J. A. at 166-67). Neither will the State subject to prior authorization "any single-source drug that fulfills a unique therapeutic function," regardless of the manufacturer's lack of participation in the Maine Rx Program. Aff. of Timothy S. Clifford, Medical Director for the Maine Bureau of Medical Services, ¶ 8 (J.A. at 147, 148-49).

D. Maine's Use of Prior Authorization Has Not Harmed Beneficiaries.

Actual experience rebuts the contention that prior authorization must harm Medicaid beneficiaries in Maine. Maine now requires prior authorization for 70 drugs in its basic prior authorization program and an additional 65 drugs if dose consolidation protocols are not followed, unconnected with the Maine Rx Program. *See* Letter from Concannon to Preston, Oct. 31, 2002 (Amici Lodging at 1).

Requiring prior authorization for certain drugs has not denied Medicaid beneficiaries necessary medicines. Any Medicaid patient given a prescription for a drug requiring prior authorization is entitled to a 96-hour supply, or a 34-day supply if the prescription is a one-time fill (not eligible for refill), prior to establishing medical necessity through the prior authorization process. *Id.* at 3. In 2001 and the first quarter of 2002, Maine paid for nearly $5.4 million of drugs in accordance with its 96-hour, 34-day policy. *Id.* at 8 (total under heading of "134 Script $").

Critical indicators by which the State might detect problems with prior authorization show that the system is operated without demonstrable harm to Medicaid patients. Although Maine is permitted by the Medicaid law up to 24 hours to respond to a request for prior authorization, the

State's average time to respond to a prior authorization request in 2002 was less than two hours. *Id.* at 2. Since Maine expanded its use of prior authorization in 2001, the number of Medicaid clients being seen by doctors is up (indicating that doctors are just as willing to see Medicaid patients as before prior authorization), the number of adverse events involving Medicaid patients is down, and the number of hospital admissions of Medicaid patients is down. *Id.* at 1-2.

The use of prior authorization by Maine and other states, whether or not in conjunction with reducing drug costs to non-Medicaid populations, is not an extraordinary approach. Rather, it mirrors drug cost management techniques used by private insurers and health maintenance organizations. *Cf.* Ruth B. Timm, Note, *The Intraenterprise Conspiracy Doctrine and the Pharmaceutical Benefit Management Industry: A Proposed Exception to the Copperweld Holding*, 31 Val. U. L. Rev. 309, 311 n.14 (1996) (stating that PBMs in the private market select drugs for a formulary based on the drug's price, effectiveness, safety and side effects, optimally selecting as the "best" drug that which is the most effective and the one most reasonably priced).

The Petitioner itself has reported this trend. A 1999 industry profile released by Petitioner showed that 90 percent of HMOs use formularies in which drugs are approved for payment based on cost, side-effects and therapeutic value. More than a third of HMOs at that time required physicians to adhere to a sequence of treatments, in most cases starting with the lowest-cost therapy. *PhRMA Eyes Delivery, Payment Methods*, Chain Drug Review, April 26, 1999, at Rx22. Drugs that are not on HMO formularies are subjected to prior authorization. For those medications, a prescribing physician must contact the HMO plan representative to request an exception before the HMO will provide coverage. United States General Accounting Office, *Prescription Drug Benefits: Impact of Medicare HMOs' Use of Formularies on Beneficiaries*, GAO-T-HEHS-99-171, July 20, 1999, at 2 (Statement of William J. Stanton before the Special Committee on Aging, U.S. Senate) (available online at *www.gao.gov*).

The State should not be faulted for adopting the prevailing market mechanism for cost containment—prior authorization—in its attempt to make prescription drugs more affordable to its uninsured and underinsured residents. Pooling the State's Medicaid population with its uninsured population to strengthen the State's bargaining position vis-à-vis drug manufacturers makes good economic and fiscal sense.

The United States agrees that using prior authorization under Medicaid to make drugs more affordable to non-Medicaid populations can further the purposes of Medicaid. Brief for the United States at 28-30. Although the United States faults Maine for not obtaining federal approval for a Medicaid plan amendment before implementing the Maine Rx Program, it concedes that that issue is not properly before this Court. Brief for the United States at 29, n.11. The Petitioner did not base its challenge on that ground or argue that issue in the proceedings below. Therefore, the issue need not be addressed by this Court. *See Paterson v. McLean*, 491 U.S. 164, 185 (1989).

II. MAINE'S USE OF ITS MARKET POWER TO NEGOTIATE REBATES FOR MAINE RX ENROLLEES DOES NOT INTERFERE WITH INTERSTATE COMMERCE.

The First Circuit was correct in holding that the Maine Rx Program "represents a novel legislative approach to one of the serious problems of our time" by empowering the State to negotiate rebates for enrollees without regulating transactions between pharmaceutical manufacturers and wholesalers or imposing excessive incidental burdens on interstate commerce. *PhRMA*, 249 F.3d at 80-82 and 84.

Commerce Clause analysis places substance over form, "eschew[ing] formalism for a sensitive case-by-case analysis of *purposes* and *effect*" of the challenged statute. *West Lynn Creamery v. Healy*, 512 U.S. 186, 201 (1994) (emphasis added). The *purpose* of the Maine Rx Program is to reduce the cost of prescription drugs for uninsured citizens by providing the same pharmaceutical benefits management (PBM) services used by private-sector PBMs to reduce costs to other segments of the market. The *effect* is to maximize the State's bargaining power vis-à-vis drug manufacturers desiring access to the Maine Rx and Maine Medicaid markets —markets unserved or underserved by private PBMs. If a manufacturer elects to not negotiate with the State, the State may react by shifting its market share away from that manufacturer's products. The effect is the same regardless of where the manufacturer is located or how it structures its chain of commerce for products destined for the Maine market.

Maine's use of its role as the PBM and payor for Medicaid recipients to leverage better prices for Maine Rx participants does not impede interstate commerce, does not distinguish between interstate and intrastate manufacturers, and does not have the practical effect of controlling prescription drug prices in other states. This simply is not the type of activity that the Commerce Clause was intended to reach. "The dormant Commerce Clause prohibits protectionist state regulation designed to benefit in-state economic interests by burdening out-of-state competitors." *Grant's Dairy-Maine, LLC v. Commissioner of Maine Dep't of Agric., Food & Rural Resources*, 232 F.3d 8, 18 (1st Cir. 2000). There is no protectionism at work here; there is only the State's compelling interest in safeguarding the health and welfare of its own residents. Indeed, because the challenged statute empowers the State to act as a market participant—not a regulator—to achieve its goals, its activities under the Maine Rx Program are not limited by the dormant Commerce Clause.

A. The Maine Rx Program Does Not Regulate Out-of-State Transactions.

A state law affecting transactions occurring outside of its borders for products clearly destined for its market should not be treated as per se invalid unless the law has the same effect as a tariff—that is, if the law gives an advantage to the enacting state's industries or destroys a competitive edge enjoyed by out-of-state industries, or has the practical effect of regulating prices in other states' markets. *West Lynn Creamery*, 512 U.S. at 193 (1994); *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 528 (1935). The Maine Rx Program does neither.

The challenged statute does not regulate manufacturer-distributor transactions, be they in-state or out-of-state. Instead, the law empowers the State to negotiate voluntary rebates from manufacturers when their products are sold at the retail level to Maine consumers who enroll in the Maine Rx Program.[4] Whether any given manufacturer-distributor transaction remains the same or changes, nothing on the face of the Maine Rx law makes it do either. "[A] statute has extraterritorial reach when it necessarily requires out-of-state commerce to be conducted according to in-state terms." *Cotto Waxo Co. v. Williams*, 46 F.3d 790, 794 (8th Cir. 1995) (finding that Minnesota statute prohibiting the sale of a product did not violate the interstate commerce clause). Like the Minnesota statute at issue in *Cotto Waxo*, the Maine statute is indifferent to the terms of manufacturer sales to distributors, or where those sales occur.

The rebates negotiated under the Maine Rx law do not necessarily change the price that a wholesaler pays a

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[4] Petitioner likening the statute's effects to a duty also ignores the voluntary character of the program and the negotiating process toward participation. Participation by manufacturers is not mandatory. It is worth noting that Petitioner did not bring a claim that the Maine statute violates the Constitutional prohibition on states imposing a duty.

manufacturer for its products or otherwise dictate any terms of the transaction. In fact, the record is devoid of any evidence to support a conclusion as to any effect on the price or profitability of manufacturer-wholesaler transactions. Increased market share may actually improve the profitability of a manufacturer that negotiates a Maine Rx rebate with the State, at the expense of a manufacturer that does not, or it may have no effect whatsoever. *See PhRMA*, 249 F.3d at 97 (Keeton, J., concurring); Andrew S. Kruliwich, *The Response to Health Care Reform by the Pharmaceutical Industry*, 50 Food & Drug L.J. 1, 4 (1995). It is not the role of the courts to speculate whether a manufacturer's profits may be adversely affected, nor does the Commerce Clause extend a constitutional protection to the profitability or market share of any individual manufacturer. *See Exxon Corp. v. Governor of Md.*, 437 U.S. 117, 127 (1978) (holding there is no Commerce Clause violation "simply because an otherwise valid regulation causes some business to shift from one interstate supplier to another").

Manufacturer-distributor sales of prescription drugs are just one link in the chain of commerce of products bound for the Maine market. Where those initial sales take place is irrelevant to any dormant Commerce Clause analysis, so long as all comparable transactions are treated equally. *See, e.g., Consolidated Cigar Corp. v. Reilly*, 218 F.3d 30, 55-58 (1st Cir. 2000) (upholding cigar advertising regulations to the extent that they are limited to the Massachusetts market, despite impact on out-of-state manufacturers); *Association of Int'l Auto. Mfgs. v. Abrams*, 84 F.3d 602, 612 (2nd Cir. 1996) (New York law requiring vehicle "bumper quality" stickers affecting out-of-state manufacturers not a per se violation of the Commerce Clause); *Toy Mfrs. of Am. v. Blumenthal*, 986 F.2d 615 (2nd Cir. 1992) (holding that state law requiring toy safety labels is not per se invalid despite effect on out-of-state manufacturers); *State of New York v. Brown*, 721 F. Supp. 629, 638-640 (D.N.J. 1989) (upholding New Jersey milk

pricing scheme despite effect on producer-distributor sales taking place in New York).

To hold otherwise would be to "allow manufacturers to avoid state regulation, under the guise of Commerce Clause protection, through marketing decisions that the manufacturers themselves create, promote, and control." *Lorillard Tobacco Co. v. Reilly*, 84 F. Supp. 2d 180, 199-200 (D. Mass. 2000), *aff'd in part and rev'd in part on other grounds, Consolidated Cigar Corp.*, 218 F.3d 30; *see also Brown*, 721 F. Supp. at 640 n.11 (stating that Court should not encourage "subterfuge" of permitting milk producers to evade New Jersey regulations by transferring ownership of milk products in New York). Indeed, some of the nation's largest prescription drug manufacturers, including SmithKline Beecham and Bristol-Myers Squibb, switched from in-state distributors to out-of-state distributors in anticipation of this litigation. *See Drug Maker Fires Back at Maine*, New York Times, Aug. 4, 2000 (First Cir. Amici App. at 131); Ed Silverman, *Maine's Radical Rx: Rural State Finds Itself Front and Center in a National Debate*, Newark Star Ledger, Oct. 8, 2000 (First Cir. Amici App. at 133).

In essence, out-of-state drug manufacturers sending their products to Maine for retail sale seek to use the Commerce Clause to secure more favorable treatment than a manufacturer located within Maine would be entitled to under the Maine Rx law. The manufacturers have conceded that the statute can constitutionally reach in-state manufacturers and even out-of-state manufacturers who sell to in-state distributors, absent any illegal benchmarking. Transcript, Hearing on Preliminary Injunction (D. Me., Oct. 19, 2000) (J. A. at 189-90). What the manufacturers seek, then, is immunity from state regulation based solely upon the situs of their transactions with distributors. Such a rigid interpretation of the dormant Commerce Clause would enable manufacturers to evade the otherwise valid exercise of a

state's authority to protect the health and welfare of its citizenry, and should not be tolerated.

Similarly, there is no evidence in the record to suggest that the Maine Rx law will have the effect of controlling prescription drug prices charged to consumers in other states. Maine's statute is easily distinguished form the Illinois law at issue in *Edgar v. Mite*, 457 U.S. 624, 642 (1982), that directly regulated business takeovers occurring outside the state; the Connecticut statute in *Healy v. Beer Institute*, 491 U.S. 324, 337-38 (1989) that prevented brewers from competitively pricing their products in Massachusetts; the New York statute in *Brown-Forman Distillers Corp., v. New York State Liquor Auth.*, 476 U.S. 573, 582 (1986), that prevented distillers who had posted prices in New York from changing their price elsewhere; or the New York statute in *Baldwin*, 294 U.S. at 521 (1935), that projected its legislation into Vermont by regulating the price to be paid for milk acquired there.

Neither is there any tying of the prices charged in Maine to the Medicaid price. The Commissioner is instructed by the statute only to use his "best efforts" to negotiate an initial rebate "equal to or greater than the rebate calculated under the Medicaid program," and later rebates "equal to or greater than the amount of any discount, rebate or price reduction for prescription drugs provided to the Federal Government." 22 M.R.S.A. §2681 (4)(B) and (C). Best efforts to negotiate do not rise to the level of price-tying.

The manufacturers' real concern here is not a burden, or a risk of a burden, to interstate commerce, either by Maine alone or by the several states through differing legislation. The "evil" perceived by the manufacturers is that other states will conclude, as has Maine, that it is within their ability and interest to use their buying power to negotiate lower

prescription drug costs for their most vulnerable residents. *Cf. Exxon Corp.*, 437 U.S. at 128.[5]

Given the evenhanded approach of the Maine Rx statute, the Court should apply a lower level of scrutiny—if any—under the dormant Commerce Clause. Using the balancing test set forth in *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970), the First Circuit correctly concluded that the State's substantial interest in "provid[ing] prescription drugs to Maine citizens who could not otherwise afford them" clearly outweighs any incidental effects the law may have on "manufacturers' possible loss of profits." *PhRMA*, 249 F.3d at 84; *see also Gary D. Peake Excavating, Inc. v. Town Board of Hancock*, 93 F.3d 68, 76 (2nd Cir. 1996) (stating that "[l]egislation pertaining to public health and safety consistently has been recognized as an important local interest").

B. The Maine Rx Law Empowers the State to Act as a Market Participant, Not a Market Regulator.

The lower courts need not have subjected the Maine Rx Program to analysis under the dormant Commerce Clause. The statutory provisions at issue here are exempt from Commerce Clause scrutiny because they empower the State to act as a market participant, not a market regulator, in order to achieve its laudable goals. Maine has long provided pharmaceutical benefits and pharmaceutical benefits management, directly and indirectly, for large segments of its citizenry, such as low-income residents and state employees, and the Maine Rx Program simply expands upon Maine's participation in the market to cover uninsured citizens who affirmatively choose to enroll in the new benefits plan. By

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[5] Petitioners did not argue in any court below that the Maine Rx Program discriminates against interstate commerce. *PhRMA*, 249 F.3d at 83. It is well established that absent the most extraordinary circumstances, legal theories not raised in any court cannot be broached for the first time on appeal. *Paterson*, 491 U.S. at 185.

empowering the State to negotiate price discounts and rebates for Maine Rx participants, and to use the threat of prior authorization under the State's Medicaid program to leverage better price rebates, the Act merely enables the State to engage in the same market behavior that private PBMs can and do use in their own commercial transactions on a regular basis.

The Commerce Clause provides "no indication of a constitutional plan to limit the ability of the states themselves to operate freely in the free market." *Reeves, Inc. v. Stake*, 447 U.S. 429, 437 (1980). Instead, the Supreme Court has "ma[d]e clear that if a State is acting as a market participant, rather than a market regulator, the dormant Commerce Clause places no limitation on its activities." *South Central Timber Dev. v. Wunnicke*, 467 U.S. 82, 93 (1984); *see also Hughes v. Alexandria Scrap Corp.*, 426 U.S. 794 (1976); *White v. Massachusetts Council of Constr. Employers*, 460 U.S. 204 (1983). To do otherwise would infringe upon "state sovereignty [and] the role of each State as guardian and trustee for its people," *White*, 460 U.S. at 207 n.3 (internal quotations omitted), and interfere with our federalist system in which "'a single courageous State may, if its citizens choose, serve as a laboratory and try novel social and economic experiments'" to solve compelling local problems. *Reeves*, 447 U.S. at 441, quoting *New State Ice. Co. v. Liebmann*, 285 U.S. 262 (1932) (Brandeis, J., dissenting).

The only relevant inquiry then is "whether the challenged 'program consitute[s] direct state participation in the market.'" *White*, 460 U.S. at 208, quoting *Reeves*, 447 U.S. at 436 n.7. That market must be "relatively narrowly defined" and constitute "'a discrete, identifiable class of economic activity in which [the State] is a major participant.'" *Wunnicke*, 467 U.S. at 97, (quoting *White*, 460 U.S. at 211 n.7; *see also National Foreign Trade Council v. Natsios*, 181 F.3d 38, 63 (1st Cir. 1999)). Furthermore, to remain on sure footing, the State's role within that market

should be limited to activities "equally available to a private party," *Rockville Centre v. Hempstead*, 196 F.3d 395, 401 (2nd Cir. 1999), and of the type commonly engaged in by private actors in that market. *See Wunnicke*, 467 U.S. at 96 (State exceeded market participant role in state timber sales by imposing contract restrictions on post-sale matters that sellers usually have no say over in the commercial context); *Natsios*, 181 F.3d at 65 ("The proper inquiry is whether [the State] is acting as an ordinary market participant would act . . . ."); *Rockville Centre*, 196 F.3d at 399 (contract restrictions imposed by municipality were "not uncommon in private transactions").

The rebate negotiation and prior authorization provisions of the Maine Rx Program clearly fit the bill. The challenged statute empowers the State to expand its long-standing participation in the discrete market of pharmaceutical benefits management services and to use its market leverage to obtain better prescription drug prices for Maine Rx enrollees. Maine, like most other states, already provides this service for statutorily defined populations. The State serves as a benefits manager for needy citizens through the Medicaid program, 22 M.R.S.A. §§3174-M and 3174-R, and for other disadvantaged, elderly or disabled citizens through the Elderly Low-Cost Drug Program, 22 M.R.S.A. §254. The Maine Rx Program extends the State's role as a PBM to another segment of Maine residents—the uninsured and underinsured—in response to a present and growing health care crisis.

With the advent of managed care, PBMs are now widely used in both the private and the public sector to assist in the purchase of prescription drugs at more advantageous prices than would otherwise be available to individual consumers or the medical plans that purchase their drugs. The PBMs obtain lower prices by negotiating rebates from drug manufacturers and/or lower reimbursement rates from retail pharmacies.

Although a modern phenomenon, PBMs operate within market principles in a classic "middle-man" role between buyers and sellers. PBMs typically contract with large employers, health maintenance organizations and other group plans to manage and administer their pharmaceutical benefits. Their control over access to large numbers of patients, and their ability to shift the market share of drugs through prior authorization lists, various types of formularies and incentives, gives the PBMs the influence they need to negotiate significant rebates from drug manufacturers. "The success of PBMs has resulted largely from their success in using consolidated purchasing power to secure rebates and discounts from drug manufacturers. . . . Drug manufacturers know that PBMs control a substantial proportion of their market share and that it is crucial to be listed favorably on the PBMs' formularies." Arnold J. Rosoff, *The Changing Face of Pharmacy Benefits Management*, 42 St. Louis U.L.J. 1, 23 (1998). "In other words, [PBMs] permit the manufacturers to make up in volume what they are losing in price." Andrew S. Kruliwich, *The Response to Health Care Reform*, 50 Food & Drug L.J. at 4 (1995).[6]

The challenged statute hews closely to the private PBM market model. The Maine Rx law expressly authorizes the State to act as a "pharmacy benefit manager" on behalf of those residents who elect to participate by enrolling in a Maine Rx consumer card program.[7] 22 M.R.S.A. §2681 (unnumbered introductory paragraph), (1), (2)(F) and (5); *see also PhRMA*, 249 F.3d at 90-91 (Keeton, J., concurring). As with a PBM in the private sector, the State negotiates with manufacturers for rebates *to itself* based on purchases by

[6] For more detail on PBMs and how they operate, *see* First Cir. Amici App. at 032-112.

[7] While enrollment is open to all Maine residents, only those residents without adequate private or government prescription drug health insurance coverage will benefit by participating.

Maine residents who enroll. 22 M.R.S.A. §2681(2)-(4). The State contracts directly with the manufacturers for the rebates that they will provide. The State then establishes discounted prices for participating pharmacies and reimburses pharmacists on a regular basis using funds from the manufacturer rebates. *Id.* at §2681(5) and (6).

In performing those functions, the State incurs substantial costs and puts its fiscal resources on the line. It advances substantial capital to cover the "float" for customer discounts, incurs the risk of manufacturers' breaches, pays processing fees to pharmacists and administers a complex web of transactions to complete the chain of price discounts, manufacturer rebates and pharmacy reimbursements.[8] *See* 22 M.R.S.A. §2681(6), (8-14). In short, the State acts just like a private-sector PBM, performing the same middle-man functions, only for a clientele that is underserved by the private market.[9] In that sense, the Maine Rx program "has substantially enlarged the market," both by expanding the role of PBMs in Maine and increasing access to prescription drugs for people who could not otherwise afford them. *Alexandria Scrap*, 426 U.S. at 815 n.* (Stevens, J., concurring); *see also* Quirion Aff. ¶¶ 5-6 (Add. of First Cir.

[8] The Legislature appropriated more than $4.5 million to a dedicated fund that provides the working capital for the reimbursements and fees, in addition to appropriations to carry out the program. 2000 Me. Legis. Ch. 786 at Sec. A-7. The rebates from the manufacturers compensate the State for the amount paid to pharmacists for the discount, but not for the professional fees paid the pharmacists. 22 M.R.S.A. §2681(5) and (6).

[9] Because a PBM's ability to negotiate rebates is based on its market power, i.e., the number of consumers to whom it can control access for a manufacturer's drugs, some private PBMs have attempted to enroll uninsured, cash-paying customers—the same market targeted by the Maine Rx Program—in consumer card programs offering discounts on drugs. Robert DiChiara *et al., Tug-of-War Over Rebates,* American Druggist, May 1997, at 44 (First Cir. Amici App. at 032, 036.) However, manufacturers have resisted those efforts by excluding those consumer card programs from rebates. *Id.* (First Cir. Amici App. at 038).

Amici Brief at 2); Moran Aff. ¶¶ 5-6 (Add. of First Cir. Amici Brief at 6); Donahue Aff. ¶¶ 2-6 (Add. of First Cir. Amici Brief at 7-8).

As with a PBM in the private sector, the State's ability to effectively bargain for manufacturer rebates to finance price discounts for Maine Rx participants stems solely from its power to deliver, or threaten to affect, market share. Consistent with the use of preauthorization lists in the private sector, the statute authorizes the State as PBM to use its ability to control market share through the threatened use of prior authorization under one benefits plan, Medicaid, to leverage better benefits for Maine Rx participants, to the extent permitted by Medicaid law. 22 M.R.S.A. §2681(7). The State uses the same type of market mechanism under its Elderly Low-Cost Drug Program to obtain price discounts for qualified seniors. *Id.* at §254(8), (8-A).

The Maine Rx provisions at issue here mirror the market mechanisms used by all private PBMs to maximize their market power. Neither empowering the State to negotiate manufacturer rebates, nor adopting the market tool of prior authorization to leverage better deals for Maine Rx participants, involves any powers unavailable to private actors. The Maine Rx provisions at issue here do not permit the State to use judicial or administrative processes for injunctive relief, to impose civil fines, or to seek criminal penalties against recalcitrant manufacturers. Nor do they regulate the price of prescription drugs for non-participating consumers in Maine. Rather, the State simply proposes to extend its economic influence over market share as the benefits manager for the Medicaid outpatient drug program to include an additional pool of lives.[10] The manufacturers'

[10] The State adopted this market-participation approach after recalling from the Governor's desk initial legislation submitted in response to the crisis in prescription drug affordability for the uninsured. *Cf.* L.D. 2599 and Committee Amendment "A" (119th Legis. 2000) (proposing to establish a Fair Drug Pricing Board to set maximum manufacturer prices for prescription drugs) (First Cir. Amici App. at 1, 22). That legislation, embodying a more regulatory approach to the problem, was passed by the Legislature but ran into opposition from Governor Angus King, who was concerned about its constitutionality. After lengthy negotiations, a compromise was reached, and the bill was recalled from the Governor's desk and amended to its present form. 119th Me. Legis. Rec., 2nd Sess., (April 26 and 28, 2000) at S-2412 and S-2476 (First Cir. Amici App. at 113-114); Francis X. Quinn, *Compromise Unveiled on Prescription Drug Bill*, Associated Press, May 11, 2000 (First Cir. Amici App. at 129).

objection to the law, therefore, is in essence a complaint that Maine chooses with whom it will deal as a benefits manager, a choice characteristic of *any* market participant.

That the State has shouldered its PBM role in order to promote the public good, rather than to make a profit or obtain for itself some other economic benefit, does not change its status as a market participant. Both *Alexandria Scrap*, 426 U.S. 794, and *Reeves*, 447 U.S. 429, "involved situations in which states 'intended their entrances [into the market] to affect the flow of commerce so as to enhance public values.'" *Natsios*, 181 F.3d at 64, *quoting* Laurence Tribe, *Constitutional Choices* 144 (1985).

Nor is there any principled reason to arbitrarily restrict "the market participation exception to acts of buying or selling" goods. *Independent Charities of Am. v. Minnesota*, 82 F.3d 791, 799 (8th Cir. 1996). The Supreme Court has applied the market participation doctrine in settings where the State did not directly buy, sell or take title to goods, *see Alexandria Scrap*, 426 U.S. at 797 (finding market participation where State paid a "bounty" to private processors to encourage destruction of scrap vehicles), and where the relevant market was for services rather than tangible goods, *see White*, 460 U.S. at 211 n.7, 214 (finding participation in construction labor market, even where City was not the direct employer of construction workers or in privity of contract with affected private subcontractors). *See also Independent Charities of*

Am., 82 F.3d at 799 (State "participating in the charitable fund raising market" entitled to restrict access to its employees in the workplace); *Rockville Centre*, 196 F.3d at 398 (town engaged in waste disposal market entitled to impose contract restrictions on towns using its services); *Swin Resource Systems v. Lycoming County, Pa.*, 883 F.2d 245, 250 (3rd Cir. 1989) (county participating in waste disposal services market permitted to give preference to county customers); *Four T's, Inc. v. Little Rock Munic. Airport Comm'n*, 108 F.3d 909, 913 (8th Cir. 1997) (upholding concession fees where town was in the market of providing facilities for rental car services).

The Maine Rx law authorizes the State to engage in a discrete, identifiable class of economic activity that is equally available to private parties, and that poses no impediment to the flow of interstate commerce. When acting as market participants, states are entitled to the same "freedoms from federal constraints, including the inherent limits of the Commerce Clause," as are private enterprises. *Reeves*, 447 U.S. at 439. The manufacturers have failed to present any evidence that Maine's strategy of pooling its market power to negotiate rebates constitutes activity unavailable to a private party.

CONCLUSION

For all of the above reasons, the Court should affirm the decision by the First Circuit Court of Appeals and lift the District Court's order preliminarily enjoining the State of Maine from implementing its Maine Rx Program.

Respectfully submitted,

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